In the Supreme Court of the United States

OCTOBER TERM, 1978

No. 78-763

GLEN L. RUTHERFORD, ET AL.,
Petitioners,

VERSUS

UNITED STATES OF AMERICA, ET AL.,
Respondents.

CROSS-PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE TENTH CIRCUIT

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November, 1978

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This Cross-Petition is brought on behalf of the Plaintiffs below for a writ of certiorari to review the judgment of the United States Court of Appeals for the Tenth Circuit.

OPINIONS BELOW

The Opinion of the Court of Appeals from which the Petition for Writ of Certiorari is requested is not yet reported but is attached as Appendix A to the Petition for Writ of Certiorari filed by the United States. The Opinion of the District Court is reported at 438 F.Supp. 1287, and is attached as Appendix D to the Petition for the Writ of Certiorari of the United States. The decision of the Commissioner of the Food and Drug Administration is reported

at 42 Fed. Reg. 39768 and is attached as Appendix E of the Petition for Writ of Certiorari of the United States. All appendices of the Petition for Certiorari filed by the United States are hereby adopted by reference for the purposes of this Cross-Petition.

JURISDICTION

The judgment of the Court of Appeals (App. B, to the Petition for Certiorari of the United States) was entered on July 10, 1978. On August 4, 1978, the Court of Appeals denied a Motion for Clarification or in the alternative Petition for Re-Hearing filed by respondents on July 27, 1978 (App. C to the Petition for Writ of Certiorari of the United States). The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

QUESTIONS PRESENTED

I.

Does the denial of the right to use Laetrile by a "terminal" cancer patient violate the constitutionally guaranteed right of privacy?

II.

Is Laetrile exempt from the Federal Food, Drug, and Cosmetic Act requirements of "efficacy" by virtue of the transitional provisions of the 1962 Amendments to the Food, Drug and Cosmetic Act allowing certain drugs to be exempted from the "efficacy" requirement if they were generally recognized as safe prior to the 1962 Amendment?

III.

Do the safety and efficacy requirements of the Federal Food, Drug and Cosmetic Act apply to drugs intended for use by the terminally ill?

CONSTITUTIONAL PROVISIONS

United States Constitution, Amendment No. 5:

"No person shall be held to answer for a capitol, or otherwise infamous crime, unless on a presentment or indictment of a Grand Jury, except in cases arising in the land or naval forces, or in the militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty or property, without due process of law; nor shall private property be taken for public use, without just compensation."

United States Constitution, Amendment No. 9:

"The enumeration in the Constitution, of certain rights shall not be construed to deny or disparage others retained by the people."

STATUTORY PROVISIONS

21 U.S.C. 321 (p), provides in part:

> "The term 'new drug' means — (1) Any drug * * * the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for the use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a 'new drug' if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use * * *."

Section 107(c)(4) of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 789 ("1962 Grandfather clause"), provides:

> "In the case of any drug which, on the day immediately preceding the enactment date [October 10, 1962], (A), was commercially used or sold in the United States, (B) was not a new drug as defined by Section 201 (p) of the basic Act as then in force [21 U.S.C. 231 (p)], and (C) was not covered by an effective [new drug] application under section 505 of that Act [21 U.S.C. 355], the amendments to section 201 (p) made by this Act shall not apply to such drug when intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug on that day."

STATEMENT OF THE CASE

This action was instituted by cancer patients on March 12, 1975, and seeks to prevent the Government from interfering with the interstate sale or distribution of Laetrile for use exclusively by "terminal" cancer patients. In an Order entered August 14, 1975, and amended October 10, 1975, the District Court enjoined the Government from preventing the purchase and subsequent interstate movement of a limited quantity of Laetrile for Glen L. Rutherford, one of the Plaintiffs. *Rutherford* v. *United States*, 399 F.Supp. 1208, 1215 (W.D. Okla. 1975).

This decision was appealed by the United States to the Tenth Circuit Court of Appeals which upheld the injunction but reached the conclusion that the Federal Food and Drug Administration probably had not developed a sufficient administrative record on the subject of Laetrile and ordered the District Court to remand the case to the Food and Drug Administration if in fact the proper record had not been developed.

At a subsequent hearing, the attorneys for the Food and Drug Administration admitted that their record was virtually non-existent and at that time, the District Court remanded the action to the Food and Drug Administration for proper administrative proceedings.

On remand to the Food and Drug Administration, an administrative proceeding was conducted and the Commissioner concluded as follows:

(a) That Laetrile is a "drug."

(b) That Laetrile is a "new drug."

(c) That Laetrile did not satisfy the premarketing approval requirements for new drugs.

(d) That there is an absence of scientifically sound data upon which experts could base an opinion that Laetrile is safe for use in man.

(e) That Laetrile did not meet the Statutory criteria of either the 1938 or 1962 Grandfather Exemption.

(f) That Laetrile is not safe and effective.

The District Court in its review of the Commissioner's decision, sustained the portions of the Commissioner's conclusion that Laetrile is not generally recognized as safe and effective but determined that Laetrile would be exempt from the Act's premarketing approval requirements by virtue of the 1962 Grandfather clause. The court further concluded that to deny the Plaintiff's use of a nontoxic substance in connection with his own personal health care offended the Constitutional right of privacy and ruled that it would be unconstitutional to deny the use of Laetrile to a "terminal" cancer patient.

This decision was appealed to the Tenth Circuit Court of Appeals which ruled as a matter of law that the "safety" and "effectiveness" requirements of the Statute as now written, have no application to terminally ill cancer patients who desire to take the drug intravenously.

The court did not rule on either the 1962 "Grandfather clause" exemption or upon the constitutional issue relied upon by the lower court.

The Appeals Court limited its ruling to "intravenous" usage of Laetrile and ignored any other form of usage of the drug.

REASONS FOR GRANTING THE CROSS-PETITION

In a well written and thoroughly researched opinion, the United States District Court for the Western District of Oklahoma examined the Commissioner's conclusions and found them wanting. The District Court ruled that Laetrile would be exempted from the efficacy requirements of the Food, Drug and Cosmetic Act by virtue of its use prior to 1962, and that the Commissioner's finding that Laetrile is a "new drug," was "arbitrary, capricious and a abuse of discretion."

The lower court found that the evidence in the administrative record established conclusively that Laetrile was "generally recognized" as safe among qualified experts prior to 1962 and therefore, qualified for the "grandfather clause exemption."[1]

However, the most compelling reason for granting this Cross-Petition for Certiorari is the failure of the Tenth Circuit Court of Appeals to rule upon the Constitutional issues raised in a lower court's decision.

The District Court's opinion was grounded upon the "right to privacy" guaranteed by the United States Constitution and in particular, the case of *Roe* v. *Wade*, 410 U.S. 113, 152, 93 S.Ct. 705, 726, 35 L.Ed.2d 147 (1973). Reference was also made to the case *Doe* v. *Bolton*, 410 U.S. 179, 213, 93 S.Ct. 739, 758, 35 L.Ed.2d 201 (1973) (concurring opinion of Justice Douglas), in which Justice

[1] Most particularly see footnotes 23 and 24 of the District Court's Opinion.

Douglas affirmed the right to privacy as encompassing the "freedom to care for one's health and person."

The District Court affirmed that the right of terminal cancer patients to utilize Laetrile falls within the "right to privacy" and vacated the Commissioner's Order.

The Court of Appeals decision expressly declined to rule on the Constitutional issue of right to privacy which was a partial basis for the ruling by the District Court. Nor did the court rule upon the exemption of Laetrile from the requirements of the Food, Drug and Cosmetics Act by virtue of the transitional provision of the 1962 amendment to that Act, often referred to as the "grandfather clause."

Additionally, the Court of Appeals decision is inconsistent within itself in that it ruled that "intravenous" Laetrile could be used by terminal cancer patients but failed to make any determination on other forms of Laetrile.

Laetrile therapy includes treatment with the liquid form of the drug initially, but later the liquid is either supplemented or combined with the tablet form.

As the Government points out in its Petition for Certiorari to this Court, the Tenth Circuit Court of Appeals did not rule upon either of the two issues decided by the lower court but instead ruled that the terms "safe" and "effective" have no real meaning for a terminal cancer patient and, therefore, that the act does not apply to their usage of Laetrile.

Although the Circuit Court tacitly accepted the constitutional conclusion reached by the lower court in its

findings that "safe" and "effective" had no application to terminal cancer patients, the court did not firmly rule on the issue.

If, in fact, the reasoning of the Court of Appeals holds true, that the safety and efficacy requirements have no application to terminal cancer patients using Laetrile, then it must logically apply across the board to both liquid and tablet forms.

The Appellate decision reads as though the sole issue brought before it were the parenteral use of Laetrile and that no argument had ever been made for usage of the tablet form. Such is far from the truth. Neither the FDA nor the Plaintiffs in this action have ever made any distinction between the two forms. The FDA has continuously been opposed to any usage of Laetrile while the Plaintiff class has continually been in favor of usage of both types.

The Court of Appeals failure to explain its limited ruling and the fact that the ruling is inconsistent within itself is sufficient grounds to justify this Court's granting of the Cross-Petition for Certiorari. The public importance of the questions presented herein justify the granting of a Writ of Certiorari, *U. S.* v. *Republic Steel Corp.*, 362 U.S. 482, 80 S.Ct. 884, 4 L.Ed.2d 903 (1960).

Respectfully submitted,

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November, 1978

CERTIFICATE OF SERVICE

I, KENNETH COE, a member of the Bar of the Supreme Court of the United States, do hereby certify that Service of the foregoing Cross-Petition for Writ of Certiorari to the United States Court of Appeals for the Tenth Circuit has been made on the required parties by depositing three (3) copies of same in the United States Mail with first class postage prepaid, to each of the following: William S. Price, Assistant U. S. Attorney, Federal Court House, Oklahoma City, Okla. 73102; Eugene M. Pfeifer, Food & Drug Administration, 5600 Fishers Lane, Rockville, Md. 20852; Julian Green, U. S. Customs Service, Regional Commissioner of Customs, 500 Dallas—Suite 1240, Houston, Tex. 77002; Wade H. McCree, Jr., Solicitor General of the United States, Washington, D.C. 20530, and Barry Grossman, Catherine G. O'Sullivan, Peter L. De La Cruz, Department of Justice, Washington, D.C. 20530, this ..... day of November, 1978.

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Kenneth Coe